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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,385	09/18/2000	THOMAS NILSSON	P239US00/AH/IO	4741

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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/664,385	Applicant(s) NILSSON ET AL.	
	Examiner Mital B. Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 8-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 3/23/04 have been fully considered but they are not persuasive.
2. In response to Applicant's arguments regarding Tarara et al (6,565,885) and the terms "electro-dose" or "electro-powder" not appearing in the reference, it should be noted that Applicant in defining an electro-dose or electro-powder in the specification sets forth properties of the powder that would allow it to be "electro" in nature. In the rejection of the claims in view of Tarara et al, the Examiner has pointed out those specific properties disclosed in Tarara et al. Furthermore, Applicant argues that the powder of Tarara et al and its properties is derived in a different manner or way from that of Applicant's. However, the Examiner emphasis that in a product claim, the process by which the product is made is not given patentable weight.
3. In response to Applicant's arguments that the present invention uses a different definition of dose porosity, again it should be noted that how that dose porosity is derived or calculated pertains to a process or method and only the end product which has specific porosity characteristics is given patentable weight. Again, Applicant states that there is a distinction between particle porosity and dose porosity. However, that distinction must be set forth structurally in a product claim rather than how that porosity was derived.

4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the metered electro-dose is not characterized by microstructures) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. The Examiner maintains that amendments to claims 3, 4, 6, and 7 still do not result in structural differences and are still directed to a process rather than an end product, and therefore the prior art rejections are maintained.

Election/Restrictions

6. Applicant's election with traverse of Group I, Claims 1-7 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the process as claimed cannot be used to make another and materially different product and the electro-dose cannot be made by another and materially different process. This is not found persuasive because the method of making the electro-dose does not have to result in the electro-dose claimed since depending on the chemical or biological substance the electro-dose will have different properties with respect to FPF, particle size, and/or porosity.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 4, 5, 6, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarara et al (US 6,565,885).

9. **As to claim 1**, Tarara teaches an electro-dose constituting a medical powder intended for use in a dry powder inhaler, the electro-dose being prepared from an electro-powder constituting an active powder substance or a dry powder medical formulation, which is metered onto a device member forming a dose carrier, giving a fine particle fraction (FPF) presenting of the order 50% or more (**See Col. 27, lines 55-64**) of its content with a particle size between 0.5-5 μm (**See Col. 23, lines 1-22, Col. 28, lines 55-57**), the dose further presenting an optimized porosity of 75 to 99.9 % (**See Col. 28, lines 35-46**).

10. **As to claims 3, 4, 6, and 7**, the recitations are directed to different processes which result in the electro-dose having a porosity between 75 and 99.9%. It should be noted that in an apparatus claim, patentable weight is given to the end product not the process and as such Tarara does teach an electro-dose having a porosity between 75 and 99.9 %. Please also note: "Even though

Art Unit: 3743

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

11. **As to claim 5**, Tarara teaches an electro-dose wherein the metered electro-dose has a height less than 800 μm (See Col. 47, lines 11-13 in which the mean volume particle diameter is disclosed; note that volume inherently encompasses height measurement).

Allowable Subject Matter

12. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

Art Unit: 3743

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

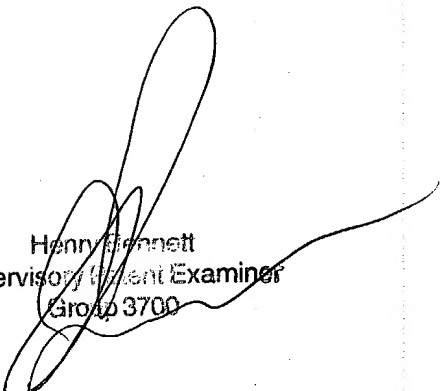
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/664,385
Art Unit: 3743

Page 7

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Art Unit 3743

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